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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,253	01/04/2006	Young Min Kong	29137.139.00	8672

7590 04/16/2008
McKenna Long & Aldridge
1900 K Street N W
Washington, DC 20006

EXAMINER

ELLIS, SUEZU Y

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,253	Applicant(s) KONG ET AL.	
	Examiner Suezu Ellis	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/28/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Korea on October 11, 2004 and October 10, 2005. It is noted, however, that applicant has not filed a certified copy of the 10-2004-0081110 and 10-2005-0094798 applications as required by 35 U.S.C. 119(b).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Examiner notes the Fig. 3 illustrates representative diameters of the zirconia and alumina particles. However, the diameter of the zirconia particles shown are 300 nm, which is not what is claimed, nor supported by the specification. Therefore, the zirconia particles having a diameter of 10-50 nm must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, it is unclear what applicant means by "secondary particle state". It is unclear if applicant means the sintered composite is no longer in the powder state? Please clarify.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasuga et al. (US 4,960,733), hereinafter referred to as Kasuga '733.

With respect to claim 9, Kasuga '733 discloses in Example 2, a method of preparing the sintered bioactive ceramic composite for implant, comprising preparing a zirconia-alumina nano-composite powder (col. 4, 5-43; col. 8, line 6-8), mixing the zirconia-alumina composite powder with an apatite-related compound (col. 2, lines 46-48; col. 4, lines 5-43), and sintering the resulting mixture (col. 4, lines 49-63).

With respect to claim 11, Kasuga '733 discloses in Example 2, Kasuga '733 discloses the mixture comprises 20 vol % of apatite-related compound and 80 vol % zirconia-alumina (col. 8, lines 11-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-8 are 35 U.S.C. 103(a) as being unpatentable over Kasuga '733 in view of Provenzano et al. (US 6,007,926).

With respect to claim 1, Kasuga '733 discloses in Examples 1, 2 and 6, comprising a zirconia-alumina nano-composite powder and an apatite-related compound, wherein zirconia primary particles and the alumina particles are sintered to form the composite in a secondary particle state (col. 2, lines 46-48; col. 4, lines 49-63). Although Kasuga '733 fails to expressly disclose the particle sizes of the alumina and zirconia being within the claimed ranges, Kasuga '733 disclose the size of the zirconia-alumina nano-composite powder being have a larger (finer) size than 200 meshes (col. 4, lines 5-43). Provenzano et al. discloses a zirconia-alumina ceramic formed from zirconia and alumina particles having particle sizes of 10 nm (col. 2, lines 35-39; col. 4, lines 32-35). It would have been obvious to one of ordinary skill in the art to modify the particle size of the alumina and zirconia particles to be about 10nm in order to provide a ceramic with a stabilized phase tetragonal phase of zirconia (col. 3, lines 40-43). It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 3-5, the modified Kasuga '733 discloses in Example 2, Kasuga '733 discloses the ceramic composite comprises 20 vol % of apatite-related compound and 80 vol % zirconia-alumina nano-composite powder (col. 8, lines 11-12).

With respect to claim 6, the modified Kasuga '733 discloses in Example 6 and Table 1, No. 2, the zirconia in the zirconia-alumina nano-composite powder is 50% by volume.

With respect to claim 7, the modified Kasuga '733 discloses in Examples 2 and 6, the zirconia-alumina nano-composite powder further comprises yttrium oxide.

With respect to claim 8, the modified Kasuga '733 discloses in Table 1, No. 2 (corresponds to Example 1) the apatite-related compound is converted into tricalcium phosphate. However, the modified Kasuga '733 fails to expressly disclose the amount of apatite-related compound that is converted. It would have been obvious to one of ordinary skill in the art to modify the amount of compound to be converted in order to create the desired amount of tricalcium phosphate.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasuga '733, in view of Provenzano et al. and further in view of Allen et al. (US 5,399,608) and further in view of Webster et al. (US 2003/0059742).

With respect to claim 10, Kasuga '733 addresses all the limitations of claim 9, however fails to expressly disclose the method of making the zirconia-alumina composite. Provenzano et al. discloses it is well known in the art to prepare the zirconia-alumina composite by mixing an alcohol and a mixed solution of zirconia and alumina, and calcining the mixture at about 600°C (col. 2, lines 27-53). Provenzano et al. fails to expressly disclose the type of alcohol used, however does disclose any alcohol can be used such that the alumina and zirconia powders are not soluble within

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the alcohol (col. 2, lines 27-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the type of alcohol used, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Both Kasuga '878 and Provenzano et al. fail to expressly disclose including a polyester network in which the zirconium and aluminum ions are trapped. Allen et al. teaches it is well known in the art to make a polyester by reacting dicarboxylic acids with glycols (polyhydric alcohol) (col. 54-64). It would have been obvious to one of ordinary skill in the art to include a dicarboxylic acid with the polyhydric alcohol in order to create a polyester matrix. Webster et al. teaches it is well known in making orthopedic/dental implants to create an implant made of zirconia-alumina nanocomposites in a polyester matrix [0025]-[0027]. It would have been obvious to one of ordinary skill in the art to create a polyester matrix in order to produce a bioactive ceramic composite with excellent mechanical properties.

Claims 1-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasuga et al. (US 5,232,878), hereinafter referred to as Kasuga '878, in view of Provenzano et al.

With respect to claims 1 and 2, Kasuga '878 discloses a sintered bioactive ceramic composite for implant, comprising a zirconia-alumina composite powder and an apatite-related compound (hydroxyapatite), wherein zirconia primary particles and the alumina particles are sintered to form the composite in a secondary particle state (col. 3,

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lines 41-60; col. 8, lines 56-58). However, Kasuga '878 fails to expressly disclose the zirconia and alumina particles having particle sizes in the claimed range. Provenzano et al. discloses a zirconia-alumina ceramic formed from zirconia and alumina particles having particle sizes of 10 nm (col. 2, lines 35-39; col. 4, lines 32-35). It would have been obvious to one of ordinary skill in the art to modify the particle size of the alumina and zirconia particles to be about 10nm in order to provide a ceramic with a stabilized phase tetragonal phase of zirconia (col. 3, lines 40-43). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 9 and 12, Kasuga '878 discloses a method of preparing the sintered bioactive ceramic composite for implant, comprising preparing a zirconia-alumina composite powder, mixing the zirconia-alumina composite powder with an apatite-related compound (hydroxyapatite), and sintering the resulting mixture (col. 3, lines 41-60; col. 8, lines 56-58). Kasuga '878 fails to expressly disclose the zirconia-alumina composite powder being a nano-composite. Provenzano et al. discloses it is well known in the art to create ceramics from a zirconia-alumina nano-composite powder (col. 2, lines 35-39; claim 1). It would have been obvious to one of ordinary skill in the art to modify the composite powder to be nano-sized in order to provide a ceramic with a stabilized phase tetragonal phase of zirconia (col. 3, lines 40-43).

With respect to claims 3-5 and 11, the modified Kasuga '878 discloses the ceramic composite can comprise 40 vol % of apatite-related compound and 60 vol % zirconia-alumina nano-composite powder (col. 10, lines 3-8).

With respect to claim 6, the modified Kasuga '878 discloses the zirconia content of the zirconia-alumina nano-composite-powder can be 95% (col. 6, lines 64-67; col. 9, lines 48-55).

With respect to claim 7, the modified Kasuga '878 discloses in Example 1, the zirconia-alumina nano-composite powder further comprises yttrium oxide.

With respect to claim 8, the modified Kasuga '878 discloses the apatite-related compound is converted into tricalcium phosphate (col. 10, lines 44-46). However, the modified Kasuga '878 fails to expressly disclose the amount of apatite-related compound that is converted. It would have been obvious to one of ordinary skill in the art to modify the amount of compound to be converted in order to create the desired amount of tricalcium phosphate.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasuga '733, in view of Provenzano et al. and further in view of Allen et al. and further in view of Webster et al.

With respect to claim 10, Kasuga '733 addresses all the limitations of claim 9, however fails to expressly disclose the method of making the zirconia-alumina composite. Provenzano et al. discloses it is well known in the art to prepare the zirconia-alumina composite by mixing an alcohol and a mixed solution of zirconia and

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alumina, and calcining the mixture at about 600°C (col. 2, lines 27-53). Provenzano et al. fails to expressly disclose the type of alcohol used, however does disclose any alcohol can be used such that the alumina and zirconia powders are not soluble within the alcohol (col. 2, lines 27-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the type of alcohol used, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Both Kasuga '878 and Provenzano et al. fail to expressly disclose including a polyester network in which the zirconium and aluminum ions are trapped. Allen et al. teaches it is well known in the art to make a polyester by reacting dicarboxylic acids with glycols (polyhydric alcohol) (col. 54-64). It would have been obvious to one of ordinary skill in the art to include a dicarboxylic acid with the polyhydric alcohol in order to create a polyester matrix. Webster et al. teaches it is well known in making orthopedic/dental implants to create an implant made of zirconia-alumina nanocomposites in a polyester matrix [0025]-[0027]. It would have been obvious to one of ordinary skill in the art to create a polyester matrix in order to produce a bioactive ceramic composite with excellent mechanical properties.

Claims 1, 2, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al.

With respect to claims 1 and 2, Webster et al. discloses bioactive ceramic composite comprising zirconia-alumina nano-composite with an apatite-related

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compound (hydroxyapatite) and sintering the resulting mixture [0019], [0022], [0035]. Webster et al. further discloses the diameters of the nanofibers can be about 20nm [0019]. Webster et al. fails to expressly disclose the zirconia-alumina nano-composite being a powder, however it would have been an obvious design choice to modify the form of the nanocomposite since such a modification would have involved a mere change in the shape of a component. A change in shape is generally recognized as being within the level of one of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

With respect to claims 9 and 11, Webster et al. discloses preparing a bioactive ceramic composite by preparing a zirconia-alumina nano-composite with an apatite-related compound (hydroxyapatite) and sintering the resulting mixture [0019],[0022], [0035]. Webster et al. fails to expressly disclose the zirconia-alumina nano-composite being a powder, however it would have been an obvious design choice to modify the form of the nanocomposite since such a modification would have involved a mere change in the shape of a component. A change in shape is generally recognized as being within the level of one of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Timing of Restriction/Elections

Applicant discloses several inventions and/or species. Applicant should be aware that a requirement for a restriction and/or election may be made at any time. Currently, the claims do not present an undue burden to the examiner. However, if

numerous complex claims are presented which are burdensome to examine, the examiner may respond with a restriction and/or election due to time constraints to ensure that the inventions and/or species are properly examined.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615